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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,493	09/16/2003	Joseph P. Errico	F-289	2440
51640 7550 09/18/2008				
SPINE MP				
LERNER, DAVID, et al.				
600 SOUTH AVENUE WEST				
WESTFIELD, NJ 07090				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
09/18/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/663,493

Applicant(s)

ERRICO ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al. (6478800) in view of Buttner-Janz et al. (5401269) and McGahan et al. (WO 01/62191). Fraser et al. disclose (Fig. 1) a spinal implant **24** and tool set **10** for implantation. Fraser shows (Fig. 4) an implant with upper and lower baseplates having perimeters. Fraser also shows (Fig. 12) the tool with corresponding distal surface **106** and a plurality of spacers or projections protruding outwardly from the distal surface to thus form a recessed engaging surface. However, Fraser et al. fail to disclose the implant's baseplates being articulatable relative to one another and that the corresponding surfaces of the baseplate and tool are angled. It is noted that Fraser discloses other spinal implants are capable of use with the tool, col. 3, lines 54-56. Buttner-Janz et al. teach (Figs. 3,4) a spinal implant with first and second plates that are articulatable and have slot on the outer surface capable of receiving a tool. McGahan et al. illustrates (Fig. 15b) a spinal orthopedic set with a spinal implant **10** with angled perimeter surfaces having a central flat surface **22** flanked by two flat corner perimeter surfaces **18**, **26** that correspond to the angled distal end of the tool having central surface **128** and two flanked flat surfaces **126**, **130** to engage the implant. McGahan teaches that angled perimeter flat surfaces are provided to prevent rotation of the implant when inserting with the tool, page 12, lines 21-24. McGahan also shows (Fig.

22B) a difference in dimension of the implant surface and the tool engaging surface. McGahan show (Figs. 29A,B) another insertion tool and implant where the corresponding angled surfaces comprise a central flat surface flanked by two adjacent flat surfaces and thus form corners. Regarding claims 13-15, since the tool is capable of being positioned about the implant in several locations, respective desired surgical approaches are capable of being used. It would have been obvious to one of ordinary skill in the art to modify the set and use an articulating implant as taught by Buttner-Janz et al. with the tool of Fraser et al. since this would provide a patient with the ability to permit motion between the vertebrae and it further would have been obvious to one of ordinary skill in the art to also utilize angled flat perimeter surfaces on the plates and tool as taught by McGahan and modify the spinal implant and tool set of Fraser et al. as modified by Buttner-Janz such that it provides the surgeon with more precise control of the spinal implant or a more "locked" fit between the tool and implant. A modification of the engaging surfaces between the tool and that of the spinal implant would be within the skill of one of ordinary skill in the art since it would not change the ability of the device's baseplates from articulating with respect to one another. Thus the modification of Fraser's tool in view of McGahan's teaching would result in having at least three flat surfaces and form at least two recessed corners.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (6368350) in view of Branch et al. (6174311). Erickson et al. disclose (Fig. 6) a spinal implant with upper and lower baseplates (20,21) having perimeters. Because the perimeters are not rounded, they can be considered to be angled. However, Erickson

et al. fail to disclose the tool used to deliver the implant's baseplates with corresponding surfaces on the tool that are angled. Branch et al. teach (Fig. 10) a tool with a spacer protruding outward from the angled surface. Since no surfaces are rounded or curved the distal surface of the tool can be considered angled. Fig. 11 shows the implant engaging angled surfaces of the tool. It would have been obvious to one ordinary skill in the art to have a tool as taught by Branch et al. that engages a perimeter of the implant of Erickson such that it provides a stable engagement for delivery.

Response to Arguments

Applicant's arguments filed 5/20/08 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching of Buttner-Janz is to provide the patient with an articulating implant. Fraser does not state that an articulating implant cannot be used, but a variety of possible types of implants can be used with the delivery tool. Applicant then argues that McGahan cannot be used as a teaching since it is a tool used on a spacer and not a moveable spinal implant. However, the implant is not what is intended to be incorporated into the system but the

corners of the implant and the corresponding structure on a tool since this formation prevents dislodgement of the implant from the tool during insertion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738